

REMARKS

I. Status of the Claims

Applicants respectfully request consideration of the amendments to the specification and claims as herein presented. Claims 1-13, 15-23, 26-39, 43, and 44 are pending and not withdrawn. Pending claims 1-4, and 37 are amended herein. Claims 24 and 40-42 have been withdrawn from consideration as claim a non-elected invention or inventions. Claims 14 and 25 have been canceled. New claims 43 and 44 have been added.

Support for the amendment to claims 1, 3, and 4 may be found, for example, in paragraphs [0068] and [0074] of the specification as filed. Support for the amendment to claim 2 may be found, for example, in paragraph [0074]. The amendment to claim 37 is merely to alter antecedence.

Support for new claims 43 is found at paragraph [0065]. Support for new claim 44 is found in original paragraph [0010] and in the SEQ ID NO listing as filed.

After carefully considering the objections and rejections raised in the Office Action mailed March 14, 2005, Applicants respectfully request reconsideration and early allowance of the amended claims herein presented.

II. Claim Rejections - 35 U.S.C. § 112, Second Paragraph

Claims 2-4, 37, and 39 stand rejected under 35 U.S.C. § 112, second paragraph, for alleged indefiniteness. Claims 2-4 and have been amended herein. Applicants contend that even if the claims were previously indefinite (something Applicants strenuously deny), in light of the currently amended claims the rejections are no longer relevant. The pDElia2_{FC5}-KDB2HL construct is described, for example, in paragraphs [0092], [0110], and [0012]. The claims are

adequately definite to satisfy the requirements of § 112. The rejection should be withdrawn and the claims allowed.

III. Claim Rejections - 35 U.S.C. § 112, First Paragraph

Claim 25 stands rejected under 35 U.S.C. § 112, first paragraph, for alleged inclusion of new matter. Applicants deny that claim 25 included new matter, and they reassert their various arguments in support of inclusion and allowance of that claim; however, in the interest of expediting prosecution, claim 25 has been cancelled. Such cancellation is made without prejudice to Applicants' ability to pursue the subject matter of that claim in further continuation or divisional applications.

Claims 3 and 4 stand rejected under 35 U.S.C. § 112, first paragraph, for alleged inclusion of new matter. Applicants respectfully traverse. Claims 3 and 4 as amended herein are fully supported by the specification as filed. Applicants respectfully submit that this "new matter" rejection is inappropriate because it misconstrues the nature of the claim. The ability to increase lysine biosynthesis is a functional limitation included to identify those variants or truncations of ORF2 that are within the invention. It is not, as characterized in the Official Action, a generic quality of those ORF2 truncations and variants that are not within the confines of the claims. The rejection should be withdrawn, and the claims should be allowed.

Claim 4 also stands rejected under 35 U.S.C. § 112, first paragraph, for alleged inclusion of new matter. The Office Action alleges that the specification does not support combination of nucleic acids as set forth in claim 4. Applicants respectfully traverse. Support for the combination of nucleic acids set forth in claim 4 may be found, for instance, in paragraph [0058], which reports a KDB2HL polypeptide, paragraph [0074], which discusses truncation within the

confines of the invention, and throughout the specification and claims as filed. Applicants further remind that there is no "in haec verba" requirement for amendment support, and that imposition of one in this case would be contrary to United States law. *See In re Wertheim*, 541 F.2d 257, 265 (C.C.P.A. 1976).

Claim 8 stands rejected under 35 U.S.C § 112, first paragraph, for alleged inclusion of new matter. Claim 8 recites:

The polynucleotide molecule of claim 1, wherein said ask and asd polypeptides are encoded by an ask/asd operon comprising a nucleotide sequence encoding two polypeptides one having ask activity and the other having asd activity, wherein said ask polypeptide is least 80% identical to SEQ ID NO:2 and said asd polypeptide is at least 80% identical to SEQ ID NO: 4 and wherein said nucleotide sequence encoding said ask polypeptide is at least 90% identical to SEQ ID NO: 1 and said nucleotide sequence encoding said asd polypeptide is at least 90% identical to SEQ ID NO: 3.

Support for claim 8 is found, for example, in paragraph [0066], which discusses incorporation of ask-asd operon elements in nucleic acid sequences, as well as [0112], which indicates that polynucleotide molecules of the invention may incorporate ask-asd elements.

Claims 1-13, 15-23, 25-33, 37, and 38 stand rejected under 35 U.S.C. § 112, first paragraph, for alleged failure to comply with the "possession" portion of the written description requirement. Applicants respectfully traverse. Possession of the genus of claim 1, as amended, is adequately demonstrated in the specification. Independent claim 1 includes percent identity limitations for nucleic acid molecules and polypeptides in that claim, as well as functional limitations for the polypeptides that are produced.

The claimed genus is well-defined, and one skilled in the art would, with the benefit of the disclosure, recognize that applicants were in possession of the claimed subject matter at the

time that the application was filed. *Regents of the University of California v. Eli Lilly*, 119 F.3d 1559, 43 U.S.P.Q.2d 1398 (Fed. Cir. 1997) is inapposite in this case. The claims herein do not make mere "generic statement[s]," because they define the nucleotide sequences and amino acid sequences by function and structure. Furthermore, the nucleotide sequences and resulting polypeptides are exemplified by structures having sequences disclosed within the specification. The rejection should be withdrawn and the claims allowed.

Claims 1-13, 15-33, 37, and 38 stand rejected under 35 U.S.C. § 112, first paragraph, for allegedly failing to "reasonably provide enablement for all polynucleotides broadly encompassed by the claims." Applicants respectfully traverse.

Analysis of the *Wands* factors leads one to conclude that the amended claims of the application are enabled. The amended claims are not as broad as stated in the Office Action. They do not cover *any* nucleotide that encodes *any* polypeptide. The claims instead recite nucleotide sequences and polypeptides defined by identity to stated sequences.

The high level of skill of those in the art also weighs in favor of enablement of the claims, as does the state of the art at the time the application was filed. The Office Action does not recognize that whereas occasionally a single mutation may affect activity, in the vast majority of cases there is not change. Conservative substitutions are known to be tolerated. In support of its conclusion that alterations of polypeptides were unpredictable at the time of the invention, the Office Action cites a single publication that was published eight years prior to the filing of the earliest application from which this case claims priority. In a rapidly advancing field such as microbiology, such a publication can not be considered relevant to show skill in the art at such a remote time from the invention.

The inventors provide adequate direction and sufficient working examples. There is no requirement for a vast multitude of working examples, particularly in an area where skill in the art is high. Furthermore, the claims, as amended, provide sufficient guidance to allow one skilled in the art to practice the invention without *undue* experimentation; Applicants respectfully note that some amount of experimentation is expected and permissible.

IV. Claim Rejections - Double Patenting

Claims 1-13, 15-23, and 25-39 stand provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over certain claims of pending United States Patent Application No. 10/771,695. Because this is a provisional rejection and both applications continue to undergo prosecution, Applicants elect not to file a terminal disclaimer at this time. They reserve the right to do so at a later date during the pendency of the applications, or in the event that the provisional nature of the rejection is removed.

CONCLUSION

Applicants respectfully submit that the amendments and remarks set forth in this paper place this Application in condition for allowance and such action is courteously requested at an early date. Prompt and favorable consideration of this Response and Amendment is respectfully requested.

AUTHORIZATION

Applicants believe that this paper is timely without the need for extension beyond the one month that is requested herein. In the event that a further extension of time is necessary to make this paper timely, one is respectfully requested. The Commissioner is hereby authorized to charge any necessary additional fees associated with this paper to Deposit Account No. 02-4553.

Respectfully submitted,

Buchanan Ingersoll PC



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Duane A. Stewart III
Registration No. 54,468
Attorney for Applicants
One Oxford Centre, 20th Floor
301 Grant Street
Pittsburgh, Pennsylvania 15219
Telephone: 412-562-1622